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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,609	03/05/2002	Adnan M. M. Mjalli	41305/271622	8253

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EXAMINER

STOCKTON, LAURA

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 09/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/091,609

Applicant(s)

M. MJALLI ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 25-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 19-24 is/are rejected.
- 7) ☒ Claim(s) 3-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9/5/02 6) ☐ Other: _____
7/30/02

DETAILED ACTION

Claims 1-38 are pending in the application.

Election/Restrictions

Applicants' election of Group I, and the species of Example 9, in the response filed May 7, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The generic concept, inclusive of the elected species of Example 9, is as follows:

Compounds of Formula (I) where R_2 is definition a) or d) {e.g., R_2 is a group of the formula $-N(R_9R_{10})$, $-NHC(O)R_9$, $-NHC(O)OR_9$ or $-NR_{27}-C(=NR_{11})NHR_{12}$ }.

The generic concept is embraced by claims 1-24.

The requirement is still deemed proper and is therefore made
FINAL.

Subject matter not embraced by the above identified generic
concept and claims 25-38 are withdrawn from further consideration
pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions.
Election was made **without** traverse in the response filed May 7, 2003.

It is suggested that in order to advance prosecution, the non-elected
subject matter be cancelled when responding to this Office Action.

Priority

It is acknowledged that Applicants are claiming the benefit of U.S.
Provisional Application 60/273,377 filed March 5, 2001. However,

compounds wherein R_3 and R_4 are independently hydrogen are not afforded the benefit of the March 5, 2001 date since the provisional application did not disclose in the specification or the claims that R_3 and R_4 are independently hydrogen.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are replete with the term “comprises” which in the manner that it is used constitutes improper Markush language. In all occurrences, “comprises” should be changed to “is” (such as under the

definition of R_1 in claim 1) or “selected from the group consisting of” (such as under the definitions of R_2 , R_3 , R_4 , R_5 , R_6 , R_7 , R_8 , etc. in claim 1). Reminder, if a group of substituents are listed under these variable definitions, the appropriate “or” or “and”, respectively, should be added before the last substituent listed.

In claims 1 and 2, an “or” is needed before the second definition of R_{13} and R_{14} (page 62, line 20; and page 66, line 15, respectively).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by:

- a) CA Registry No. 366489-63-6, November 2, 2001;
- b) CA Registry No. 366489-61-4, November 2, 2001;
- c) CA Registry No. 366489-58-9, November 2, 2001;
- d) CA Registry No. 366489-56-7, November 2, 2001;
- e) CA Registry No. 366489-47-6, November 2, 2001;
- f) CA Registry No. 366489-45-4, November 2, 2001;
- g) CA Registry No. 366489-42-1, November 2, 2001;
- h) CA Registry No. 366489-40-9, November 2, 2001;
- i) CA Registry No. 338410-76-7, May 25, 2001;
- j) CA Registry No. 338410-71-2, May 25, 2001;
- k) CA Registry No. 338410-59-6, May 25, 2001;
- l) CA Registry No. 338410-56-3, May 25, 2001;
- m) CA Registry No. 338410-55-2, May 25, 2001; and
- n) CA Registry No. 338410-51-8, May 25, 2001.

Each of the above cited prior art disclose compounds embraced by the instant claimed invention.

Claims 1, 2 and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by:

- a) CA Registry No. 138369-72-9, January 18, 1992;
- b) CA Registry No. 138369-70-7, January 18, 1992;
- c) Mengelberg, {CA 53:15063h, 1959} – see, for example, the compound of CA Registry No. 102001-37-6;
- d) Salgaonkar et al. {Indian Drugs (2000), 37(11), pages 547-550} – see, for example, compound No. 1 in Table I on page 549;
- e) Balboni et al. {CA 134:66089, 2000} – see, for example, the compound of CA Registry No. 59592-32-4;
- f) Yatabe et al. {WO 98/27108 – pages 1-9, 28, 30, 31, 38, 39,

65 and 66 only} – see, for example, Preparation No. 62
on page 65 (the compound of CA Registry No. 209526-
30-7 in CA 129:95714, 1998;

- g) Hoorn et al. {CA 127:336363, 1997} – see, for example, the
compound of CA Registry No. 59592-39-1;
- h) Xue et al. {U.S. Pat. 5,703,092} – see Example 410 in Table
3 in column 37 (CA Registry No. 184685-05-0);
- i) Casella et al. {CA 122:95181, 1995} – see the compound of
CA Registry No. 160322-31-6;
- j) Varney et al. {Journal of Medicinal Chemistry (1994),
37(15), pages 2274-2284} – see, for example, the fourth
compound bolded listed in column 1 on page 2282;
- k) Nawwar et al. {CA 119:250416, 1993} – see, for example, the
compound of CA Registry No. 151266-64-7;
- l) Crane et al. {CA 116:50261, 1992} – see, for example, the
compound of CA Registry No. 138369-71-8;
- m) Cuadro et al. {CA 109:128908, 1988} – see the compound of

CA Registry No. 116423-78-0;

- n) Kamdar et al. {CA 109:128903, 1988} – see, for example, the compound of CA Registry No. 31419-17-7;
- o) Aminabhavi et al. {CA 107:23674, 1987} – see, for example, the compound of CA Registry No. 108787-15-1;
- p) Nandi et al. {CA 106:138323, 1987} – see, for example, the compound of CA Registry No. 107313-45-1;
- q) Ohtani et al. {CA 87:178868, 1977} – see, for example, the compound of CA Registry No. 60603-49-8;
- r) Maekawa et al. {CA 85:154963, 1976} – see, for example, the compound of CA Registry No. 60603-43-2;
- s) Tiwari et al. {CA 85:46510, 1976} – see, for example, the compound of CA Registry No. 60121-61-1;
- t) Maekawa et al. {CA 85:21787, 1976} – see, for example, the compound of CA Registry No. 59592-12-0;
- u) Schubert et al. {CA 81:120538, 1974} - see, for example, the compound of CA Registry No. 31419-14-4;

- v) Gualtieri et al. {Journal of Medicinal Chemistry (1972),
15(4), pages 420-422} – see, for example, Example 3 in
Table 1 on page 421;
- w) Schubert et al. {CA 74:111961, 1971} – see, for example, the
compound of CA Registry No. 31419-12-2;
- x) Kanaoka et al. {CA 72:55332, 1970} – see, for example, the
compound of CA Registry No. 25810-59-7;
- y) Chimetron {FR 1,476,560} – see, for example, compound 6
in column 2 at the bottom of page 2;
- z) Aryuzina et al. {CA 66:94952, 1967} – see, for example, the
compound of CA Registry No. 13745-30-7; and
- aa) Johnson {U.S. Pat. 3,255,202} – see, for example,
compound IV in Table I in columns 9-10.

Each of the above cited prior art disclose at least one compound
that is embraced by the instant claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yatabe et al. {WO 98/27108 }, Xue et al. {U.S. Pat. 5,703,092}, Chimetron {FR 1,476,560} and Johnson {U.S. Pat. 3,255,202}, each taken alone or in combination with each other when similar utilities are asserted.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim benzimidazole compounds. Yatabe et al. (pages 1-5, 28 and 31; and especially Preparation 62 on page 65), Xue et al. (columns 5, 6 and 38-40; and especially Example 410 in Table 3 in column 37), Chimetron (page 1, column 1; page 2, column 1; and especially compound 6 in column 2 at the bottom of page 2) and

Johnson (columns 1 and 2; and especially compound IV in Table I in columns 9-10) each teach benzimidazole compounds which are either structurally the same as (see above 102 rejections) or structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of “some” among “many” is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g. an anti-convulsant).

One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful as, for example, an anti-convulsant. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Allowable Subject Matter

The elected species of Example 9 is allowable over the art of record.

Claims 3-18 are objected to as being dependent upon a rejected base claim, but would be allowable over the art of record if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

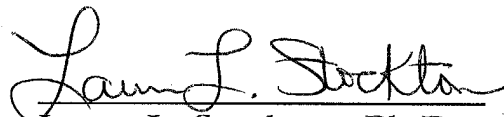
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in cursive script that reads "Laura L. Stockton". The signature is written in dark ink and is positioned above the printed name.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

August 29, 2003